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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,371	07/31/2003	Ralph A. Heasley	287.1006	2138

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/631,371	HEASLEY ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,27 and 29-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,27 and 29-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/05/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114, IDS, amendment and remarks filed 12/17/07. Claims 25, 32, 35, 36 and 37 are amended. Claims 25, 27 and 29-37 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/07 has been entered.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 25, 27 and 29-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

4. Amended claims 25, 32 and 35-37 require the release of tranexamic acid to occur over a period of about 120. However, the amendment to claims 25, 32, 35, 36 and 37 requiring the release of the tranexamic acid to occur over a period of about 120 minutes is not envisioned at the time the original specification was filed. What was envisioned is a release over an extended period of about 60 minutes to about 120 minutes. Lines 17-19 of page 7 of the specification specifically states: "thus, tranexamic acid release occurs at a controlled rate over an extended period, e.g., about 60 minutes to about 120 minutes." Thus the recitation of release occurring at over a period of about 120 minutes introduces new matter into the claims.

The above rejection can be overcome by removing the new matter from the claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 25, 27, 29-33 and 35-37 are rejected under 35 U.S.C. 102(b) as anticipated by Fujimura et al. (US 5,506,264) or 1996 PDR on Tranexamic acid (CYKLOKAPRON).

The invention in claims 25, 32 and 35-37 orally administers effective amount of delayed release pharmaceutical (claim 37), extended release pharmaceutical (claim 35) and effective amount of pharmaceutical to effect reduction of gastrointestinal side effects.

Delayed release and extended release are forms of controlled/sustained release governed

by the excipients included with the active agents in the formulation, either as a matrix material or as coating material.

Fujimura discloses tranexamate compound or tranexamic acid salt formulated with appropriate excipient or carrier or diluents in the form of tablets, capsules, granules and powders for oral administration (title, abstract, column 2, lines 24-29) meeting claims 25, 31, 32, 35-37; the daily dose is 300 to 2,000 mg that is divided into three to four doses meeting claims 29 and 30; the compound is administered orally as anti-gastric/duodenal ulcer activity, anti-gastritis/duodenitis activity (column 2, lines 20-24) meeting claim 33. Claim 27 recites the properties of the composition that is administered so that Fujimura meets that claim.

The 1996 PDR on the tranexamic acid at pages 1950 and 1951 discloses tablet that contains 500 mg tranexamic acid formulated with excipients such as microcrystalline cellulose, talc, magnesium stearate, silicon dioxide and povidone meeting claims 25, 29, 31, 32, 35-37; the formulation is contemplated for 3-4 time administration meeting claim 30; claim 27 recites the properties of the dosage form and the 1996 PDR formulation of tranexamic acid meets claim 27.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 25, 27 and 29-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujimura et al. (US 5,506,264) or 1996 PDR on Tranexamic acid (CYKLOKAPRON) in view of Cooper et al. ("A randomized comparison of medical and hysteroscopic management in women consulting a gynecologist for treatment of heavy menstrual loss," in British journal of Obstetrics and Gynecology, vol. 104, pp 1360-1366, 1997) or Bonnar et al. ("Treatment of menorrhagia during menstruation: randomized controlled trial of ethamsylate, mefenamic acid, and tranexamic) in the BMJ 1996; 313:579-582 (7 September) or Callender et al. ("treatment of Menorrhagia with Tranexamic Acid. A Double-blind Trial" in British Medical Journal, 1970, 4, 214-216).

Claims 25, 27, 29-33 and 35-37 are rejected above as being anticipated by Fujimura et al. (US 5,506,264) or 1996 PDR on Tranexamic acid (CYKLOKAPRON). However, neither Fujimura nor the PDR reference teaches claim 34, which provides the tranexamic acid containing composition to a patient having menorrhagia. But it is known to treat menorrhagia with tranexamic acid according to i) Cooper, who discloses that bloating is one of the symptoms of one who is suffering from menorrhagia and that tranexamic acid is known to be administered to persons having menorrhagia (pp 1360-1365), ii) Sheila and iii) Bonnar who disclose treating menorrhagia with tranexamic acid. Therefore, taking the teachings of the references together, one having ordinary skill in the art at the time the invention was made would have reasonable

expectation of success that administration of the tranexamic acid dosage forms of Fujimura and the 1996 PDR to a person in need thereof would treat menorrhagia according to Cooper, Sheila and Bonnar.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/

Examiner, Art Unit 1618